

Exhibit 12

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 : MDL NO. 2804
10 APPLIES TO ALL CASES :
11 : CASE NO.
12 : 17-MD-2804
13 :
14 :

15 - HIGHLY CONFIDENTIAL -
16 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
17 VOLUME I

18 - - -

19 May 16, 2019

20 - - -

21 Videotaped deposition of
22 DR. SETH B. WHITELOW, taken pursuant to
23 notice, was held at the offices of Golkow
24 Litigation Services, One Liberty Place,
25 1650 Market Street, Philadelphia,
26 Pennsylvania beginning at 9:18 a.m., on
27 the above date, before Michelle L. Gray,
28 a Registered Professional Reporter,
29 Certified Shorthand Reporter, Certified
30 Realtime Reporter, and Notary Public.

31 - - -

32 GOLKOW LITIGATION SERVICES
33 877.370.3377 ph | 917.591.5672 fax
34 deps@golkow.com

<p style="text-align: right;">Page 833</p> <p>1 an opinion on the effectiveness of its 2 compliance program is Mallinckrodt, 3 correct?</p> <p>4 A. Mallinckrodt is the only 5 manufacturer in my report, sir.</p> <p>6 Q. So the answer to that 7 question is yes?</p> <p>8 A. The answer to that question 9 is yes.</p> <p>10 Q. Thank you. You do not 11 intend to offer an opinion at this time 12 regarding any other manufacturer's 13 compliance program, correct?</p> <p>14 A. Not at this time.</p> <p>15 Q. You do not intend to offer 16 an opinion regarding the application of 17 your opinions regarding the standards 18 surrounding the design, implementation, 19 and operation of controlled substances 20 compliance programs to any other 21 manufacturers program at this time, 22 correct?</p> <p>23 MR. BOGLE: Object to form. 24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 835</p> <p>1 Q. But you didn't review their 2 suspicious order monitoring program, 3 correct?</p> <p>4 A. No. There's no review of 5 another manufacturer's suspicious order 6 monitoring program in my report.</p> <p>7 Q. All right. So I think I 8 have an understanding of kind of the 9 opinions at a high level. I'd like to 10 discuss just a couple of questions 11 regarding opinions you're not offering. 12 Okay?</p> <p>13 A. Sure.</p> <p>14 Q. So you stated earlier today 15 that you're here as a compliance expert, 16 so you are not drawing legal conclusions, 17 correct?</p> <p>18 A. Yes, sir, that is correct.</p> <p>19 Q. So you're not offering a 20 legal conclusion as to whether any 21 defendant violated the Controlled 22 Substances Act, correct?</p> <p>23 A. That is correct.</p> <p>24 Q. You are not offering a legal</p>
<p style="text-align: right;">Page 834</p> <p>1 Q. Do you want me to start 2 again?</p> <p>3 A. Yeah, and read it a bit 4 slower or at least give me something to 5 look at it because that's an awful lot 6 of -- that's a whole mouthful of words.</p> <p>7 Q. Let's -- we'll strike that 8 one.</p> <p>9 You do not intend to offer 10 any opinions regarding any other 11 manufacturer defendant in this litigation 12 at this time, correct?</p> <p>13 A. Not at this time.</p> <p>14 Q. And there is nothing in your 15 report regarding any other manufacturer 16 of controlled substances other than 17 Mallinckrodt, correct?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: No, I think 20 that's inaccurate. There are a 21 couple references in my report to 22 Endo and Purdue up in the front of 23 the report. 24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 836</p> <p>1 conclusion as to whether any defendant 2 violated the SOM regulation?</p> <p>3 A. Correct.</p> <p>4 Q. And when you were questioned 5 earlier today by Cardinal's counsel, you 6 stated that the question of whether any 7 of Cardinal's products were diverted was 8 outside the scope of your report.</p> <p>9 Is the same true for 10 Mallinckrodt's products?</p> <p>11 A. The same holds true for 12 Mallinckrodt, yes.</p> <p>13 Q. And is the same true for all 14 of the distributors and manufacturers in 15 your report's box?</p> <p>16 A. Could you give me the 17 question again, please?</p> <p>18 Q. Yes. No problem.</p> <p>19 Understood.</p> <p>20 With respect to Cardinal 21 earlier today, you stated that the 22 question of whether any product was 23 diverted was outside the scope of your 24 report. Is the same true for all of the</p>

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1 distributors, pharmacies and
 2 manufacturers that you reviewed?
 3 A. Again, as I said, same thing
 4 for Cardinal I would say for every other
 5 defendant is the same. I looked at the
 6 policies and the process and the systems,
 7 and that is what I'm rendering my -- my
 8 opinions on.
 9 Q. So the answer to that is
 10 yes?
 11 A. The answer to that is I'm
 12 not making statements about whether any
 13 particular order was diverted or not
 14 diverted.
 15 Q. Thank you, sir.
 16 Now, sir, in evaluating the
 17 effectiveness of Mallinckrodt's
 18 compliance program, you utilized the
 19 methodology that have used -- that you
 20 have used during the last 30 years when
 21 auditing or investigating compliance
 22 issues; is that correct?
 23 A. I think that's a fair way of
 24 characterizing it, yes.

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1 Q. So I want to -- I want to
 2 understand a little bit more about the
 3 methodology that you've used in your
 4 30 years of experience.
 5 A. Sure.
 6 Q. What is your practice
 7 generally when you select data or
 8 documents for a sample?
 9 MR. BOGLE: Object to form.
 10 Vague and ambiguous.
 11 BY MR. DAVISON:
 12 Q. Let me see if I can narrow
 13 it down for you. I'll withdraw that
 14 question.
 15 A. That would be real helpful.
 16 Q. No problem.
 17 Generally in your
 18 experience, when you're selecting data or
 19 documents to review, do you do a random
 20 sample?
 21 MR. BOGLE: Object to form.
 22 THE WITNESS: You're still
 23 going to have to narrow it down
 24 further.

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1 BY MR. DAVISON:
 2 Q. Are you familiar with OIG
 3 toolkits and resources like RAT-STATS to
 4 select random samples?
 5 A. I am familiar with what
 6 those are, yes.
 7 Q. Okay. And that's a way to
 8 select random samples of data or
 9 documents for review, correct?
 10 A. But it's not a way of
 11 utilizing and looking at process systems
 12 and process and controls for compliance
 13 programs, per se. That's not how we
 14 do -- that's not how I do that, no.
 15 Q. So when you're looking at
 16 processes and controls for compliance
 17 programs, you do not use random sampling?
 18 A. No. I actually ask you what
 19 the standards are that you're doing and
 20 how are you working against those
 21 standard and show me how those are
 22 actually working.
 23 Q. Okay. So talking about what
 24 you specifically reviewed today and as

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1 part of your methodology. It's fair to
 2 say that you reviewed a number of
 3 standard operating procedures; is that
 4 correct?
 5 A. I reviewed a number of
 6 documents that were supposed -- that were
 7 purported to be standard operating
 8 procedures or draft standard operating
 9 procedures, yes.
 10 Q. And you also reviewed
 11 e-mails for each of the individual
 12 manufacturers, distributors, pharmacies,
 13 that you looked at, internal e-mails?
 14 A. E-mails were part of it.
 15 Q. And generally, in your
 16 compliance history, one way of gaining
 17 information would be to interview
 18 employees of a client, correct?
 19 A. That is one way to do it,
 20 yes.
 21 Q. And -- and here I understand
 22 there weren't interviews, but you
 23 reviewed deposition transcripts. Is that
 24 fair?